

TB-STAIN COLD KIT

The kit contains:

TB Carbol Fuchsin reagent

TB Decolorizer

TB Malachite Green reagent

Trading name:	TB CARBOL FUCHSIN REAGENT				
Product code:	TBC-OT-X**	Date of compilation:	21 Dec 2022	Version:	5





SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1	Product identifier	
	Trading name:	TB CARBOL FUCHSIN REAGENT
	Chemical name:	-
	Catalogue number:	TBC-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use in TB-Stain Cold, TB-Stain Hot kit and TB-Stain Quick kits.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.
1.3	Details of the supplier of the safety data sheet	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Telefax.:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2. Hazards identification

2.1	Classification of the substance or mixture	
2.1.1	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statements*:
	Flam. Liq. 3	H226
	Muta. 2	H341
	Acute Tox. 3	H331
	Acute Tox. 3	H311
	Acute Tox. 3	H301
	Skin. Corr. 1B	H314
	STOT RE 2	H373
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see SECTION 16		

Trading name:	TB CARBOL FUCHSIN REAGENT				
Product code:	TBC-OT-X**	Date of compilation:	21 Dec 2022	Version:	5

2.2	Label elements	
	Product identification:	TB CARBOL FUCHSIN REAGENT
	Identification number:	-
	Authorization number:	-
	Hazard pictograms:	<div style="display: flex; flex-wrap: wrap; justify-content: space-around;"> <div style="text-align: center;">  GHS02 </div> <div style="text-align: center;">  GHS05 </div> <div style="text-align: center;">  GHS06 </div> <div style="text-align: center;">  GHS08 </div> </div>
	Signal word:	Danger
	Hazard statements:	<p>H226 Flammable liquid and vapor.</p> <p>H314 Causes severe skin burns and eye damage.</p> <p>H301 Toxic if swallowed.</p> <p>H311 Toxic in contact with skin.</p> <p>H331 Toxic if inhaled.</p> <p>H341 Suspected of causing genetic defects.</p> <p>H373 May cause damage to organs through prolonged or repeated exposure.</p>
	Precautionary statements:	<p>P210 Keep away from heat/sparks/open flames/hot surfaces. - Do not smoke.</p> <p>P233 Keep container tightly closed.</p> <p>P280 Wear protective gloves/protective clothing/eye/protection/face protection.</p> <p>P302+P352 IF ON SKIN: Wash with plenty of water and soap.</p> <p>P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P308+P311 IF exposed or concerned: Call a POISON CENTER or doctor.</p>
	Supplemental hazard information (EU):	-
2.3	Other hazards	

Trading name:	TB CARBOL FUCHSIN REAGENT				
Product code:	TBC-OT-X**	Date of compilation:	21 Dec 2022	Version:	5

<p>Endocrine Disrupting Properties: No known endocrine disrupting properties</p> <p>Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.</p>

SECTION 3. Composition/information on ingredients

CAS/EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610-43-0147	10 - 20 %	ethanol	Flam. Liq. 2; H225
107-21-1/ 203-473-3/ 603-027-00-1	-	10 - 20 %	ethylene glycol	Acute Tox. 4; H302
108-95-2/ 203-632-7/ 604-001-00-2	01-2119471329-32-xxxx	4 -5 %	phenol	Acute Tox. 3; H301 Acute Tox. 3; H311 Acute Tox. 3; H331 Skin Corr. 1B; H314 Muta. 2; H341 STOT SE 2; H373

SECTION 4. First aid measures

4.1	Description of first aid measures	
	General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.
	Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. In case of difficult breathing, provide the afflicted person with oxygen.
	Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water for at least 20 minutes. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact:	Rinse out with plenty of water with the eyelid held wide open for at least 20 minutes. If the symptoms remain, immediately call in ophthalmologist.
	Following ingestion:	Rinse the mouth thoroughly with 1-2 glasses of water. Immediately consult a physician and show the container or label. In case of swallowing large quantities, transport the afflicted person to the hospital.
	Self-protection of the first aider:	-
4.2	Most important symptoms and effects, both acute and delayed	

Trading name:	TB CARBOL FUCHSIN REAGENT				
Product code:	TBC-OT-X**	Date of compilation:	21 Dec 2022	Version:	5

	Following inhalation:	Depending on concentration and exposure time, it may lead to mucosa irritation, cough, and dyspnea.
	Following skin contact:	Depending on concentration and exposure time, it may lead to irritation, rash, skin drying and skin cracking.
	Following eye contact:	Depending on concentration and exposure time, it may lead to irritation, tearing, redness and pain.
	Following ingestion:	Depending on concentration and exposure time, it may lead to stinging and digestive mucus damage, abdominal pain, nausea, vomiting.
4.3	Indication of any immediate medical attention and special treatment needed	
	-	

SECTION 5. Firefighting measures		
5.1	Extinguishing media	
	Suitable extinguishing media:	Water, foam, dry powder, CO ₂
	Unsuitable extinguishing media:	No information available
5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Mixture with combustible ingredients. Forms explosive mixtures with air at elevated temperatures. Development of hazardous combustion gases or vapours possible in the event of fire. Vapours are heavier than air and may spread along floors.
5.3	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing.	
5.4	Additional information	
	Cool endangered receptacles with water spray. Collect contaminated fire fighting water separately. Do not contaminate the environment with extinguishing media.	

SECTION 6. Accidental release measures		
6.1	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Avoid breathing vapors and avoid contact with skin and eyes. Do not smoke. Keep away from ignition sources.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Use protective equipment; in case of inadequate ventilation use adequate airways protective equipment (see Section 8).	
6.2	Environmental precautions:	

Trading name:	TB CARBOL FUCHSIN REAGENT				
Product code:	TBC-OT-X**	Date of compilation:	21 Dec 2022	Version:	5

	Do not let product enter drains. Risk of explosion.	
6.3	Methods and material for containment and cleaning up	
6.3.1.	Bundling, covering of drains; capping procedures:	Cover drains. Collect, bind, and pump off spills.
6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using absorbing material. Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and involved materials with water.
6.3.3.	Other information:	Secure proper ventilation. Do not use incompatible materials (see Section 10).
6.4	Reference to other sections	
	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.	

SECTION 7. Handling and storage		
7.1	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharge. Do not smoke.
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	Protect against electrostatic charges.
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms at temperatures ranging from 15 to 25 °C. Protect from heat and direct sunlight.
	Packaging materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.

Trading name:	TB CARBOL FUCHSIN REAGENT				
Product code:	TBC-OT-X**	Date of compilation:	21 Dec 2022	Version:	5

Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 10).
7.3 Specific end use(s)	
Recommendations:	-
Industrial sector specific solutions:	-

SECTION 8. Exposure controls/personal protection

8.1 Control parameters

Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
Ethanol	64-17-5	1000/-	1900/-	-
Ethylene glycol	107-21-1	20/40	52/104	
Phenol	108-95-2	2/4	8/16	120 mg/g of creatinine (0.14 mol/mol of creatinine), end of shift, urinary excretion

Substance name:	-
EC No:	-
CAS No:	-

DNEL

Industrial

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	1900 mg/ m ³ (ethanol)	-	35 mg/kg (ethylene glycol)	380 mg/m ³ (ethanol) 8 mg/m ³ (phenol)
Dermal	-	-	-	343 mg/kg (ethanol) 106 mg/kg (ethylene glycol) 1.23 mg/kg (phenol)

Critical physical parameters: solubility, flammability, corrosivity:	-
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Consumer

Trading name:	TB CARBOL FUCHSIN REAGENT				
Product code:	TBC-OT-X**	Date of compilation:	21 Dec 2022	Version:	5

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	87 mg/kg (ethanol) 0.5 mg/kg (phenol)
Inhalation	950 mg/ m ³ (ethanol)	-	7 mg/kg (ethylene glycol)	114 mg/m ³ (ethanol) 0.452 mg/m ³ (phenol)
Dermal	-	-	-	206 mg/kg (ethanol) 0.5 mg/kg (phenol) 53 mg/kg (ethylene glycol)

PNEC

Environmental protection target	PNEC
Fresh water	0.96 mg/l (ethanol) 10 mg/l (ethylene glycol) 0.0077 mg/l (phenol)
Freshwater sediments	3.6 mg/kg (ethanol) 37 mg/kg (ethylene glycol) 0.09125 mg/kg (phenol)
Marine water	0.79 mg/l (ethanol) 1 mg/l (ethylene glycol) 0.00077 mg/l (phenol)
Marine sediments	2.9 mg/kg (ethanol) 3.7 mg/kg (ethylene glycol) 0.00915 mg/kg (phenol)
Food chain	380-720 mg/kg (ethanol)
Microorganisms in sewage treatment	580 mg/l (ethanol) 199.5 mg/l (ethylene glycol) 2.1 mg/l (phenol)
Soil (agricultural)	0.63 mg/kg (ethanol) 1.53 mg/kg (ethylene glycol) 0.136 mg/kg (phenol)
Air	no information available

8.2 Exposure controls

8.2.1. Appropriate engineering controls

Substance/mixture related measures to prevent exposure during identified uses:

Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.

Trading name:	TB CARBOL FUCHSIN REAGENT				
Product code:	TBC-OT-X**	Date of compilation:	21 Dec 2022	Version:	5

	Structural measures to prevent exposure:	In accordance with Section 7.
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels. Secure stations for rinsing eyes and showering.
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (EN 166) or visor in case of lower levels of concentration in air; protective gas mask that covers the entire face in case of higher levels of concentration in air.
8.2.2.2.	Skin protection	
	Hand protection:	<p>The protective gloves have to satisfy the specification of Regulation (EU) 2016/425 and the related standard EN 374.</p> <p>Full contact:</p> <ul style="list-style-type: none"> Glove material: butyl rubber Glove thickness: 0.70 mm Break through time: > 480 min <p>Splash contact:</p> <ul style="list-style-type: none"> Gloves material: nitrile rubber Glove thickness: 0.40 mm Break through time: > 120 min
	Other skin protection:	During everyday work use cotton clothing (EN 340) and suitable footwear, such as rubber boots (EN 20345) or shoes that cover the entire foot. In case of spilling hazard, use clothing made of impermeable material suitable for protection from liquid chemicals (Viton, PVC, himex) and footwear made from the same material.
8.2.2.3.	Respiratory protection:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) according to EN 14387) used when concentration levels exceed GVI.
8.2.2.4.	Thermal hazards:	No information available
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

Trading name:	TB CARBOL FUCHSIN REAGENT				
Product code:	TBC-OT-X**	Date of compilation:	21 Dec 2022	Version:	5

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

		Value	Method
	Physical state:	liquid	No information available
	Colour:	dark pink	No information available
	Odour/odour threshold:	phenol like/no information available	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	48°C	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	No information available	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density:	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available

9.2 Other information

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SECTION 10. Stability and reactivity

10.1	Reactivity:	See subsections 10.3 through 10.5.
10.2	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using (room temperature).
10.3	Possibility of hazardous reactions:	No information available
10.4	Conditions to avoid:	Heating.
10.5	Incompatible materials:	No further relevant information available.
10.6	Hazardous decomposition products:	No dangerous decomposition products known.

Trading name:	TB CARBOL FUCHSIN REAGENT				
Product code:	TBC-OT-X**	Date of compilation:	21 Dec 2022	Version:	5

SECTION 11. Toxicological information					
11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008					
Acute toxicity:					
Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results
Oral:	-	rat	LD ₅₀	-	10.470 mg/kg (ethanol) 7.712 mg/kg (ethylene glycol)
Dermal:	-	rat	LD ₅₀	-	>3.500 mg/kg (ethylene glycol) 660 mg/kg (phenol)
Inhalation:	-	rat	LC ₅₀	4 h	124.7 mg/l (ethanol)
Specific target organ toxicity – single exposure (STOT SE):					
	Specific effects		Target organ		Note
Oral:	No information available		No information available		-
Dermal:	No information available		No information available		-
Inhalation:	No information available		No information available		-
Aspiration hazard:					
	No information available.				
Irritation and corrosion					
	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation:	-	in vitro study	-	OECD 431	causes burns (phenol)
Serious eye damage/irritation	-	rabbit	-	OECD 405	corrosive (phenol)
Sensitization					
Skin sensitization:	No information available.				
Respiratory sensitization:	No information available.				
Symptoms related to the physical, chemical and toxicological characteristics					
Oral exposure:	No information available.				
Dermal exposure:	No information available.				
Inhalation exposure:	No information available.				
Eye exposure:	No information available.				

Trading name:	TB CARBOL FUCHSIN REAGENT				
Product code:	TBC-OT-X**	Date of compilation:	21 Dec 2022	Version:	5

Repeated dose toxicity (subacute, subchronic, chronic)						
	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Specific target organ toxicity – repeated exposure (STOT RE):						
	Specific effects		Target organ		Note	
Subacute oral	No information available		No information available		-	
Subacute dermal	No information available		No information available		-	
Subacute inhalation	No information available		No information available		-	
Subchronic oral	No information available		No information available		-	
Subchronic dermal	No information available		No information available		-	
Subchronic inhalation	No information available		No information available		-	

Trading name:	TB CARBOL FUCHSIN REAGENT				
Product code:	TBC-OT-X**	Date of compilation:	21 Dec 2022	Version:	5

Chronic oral	No information available	No information available	-
Chronic dermal	No information available	No information available	-
Chronic inhalation	No information available	No information available	-

CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)	
Carcinogenicity:	Based on available data, the classification criteria are not met.
Mutagenicity <i>in vitro</i> :	Based on available data, the classification criteria are not met.
Genotoxicity:	Based on available data, the classification criteria are not met.
Mutagenicity <i>in vivo</i> :	Based on available data, the classification criteria are not met.
Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
Reproductive toxicity:	Based on available data, the classification criteria are not met.
Summary of evaluation of the CMR properties:	
Based on available data, the classification criteria are not met.	

11.2	Information on other hazards:
11.2.1.	Endocrine disrupting properties:
	No known endocrine disrupting properties that affect human health.
11.2.2.	Other information:
	-

SECTION 12. Ecological information

12.1 Toxicity						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	Leuciscus idus (Golden orfe; ethanol) Oncorhynchus mykiss (rainbow trout; phenol)	-	-	8.140 mg/l (ethanol) 72.860 mg/l (ethylene glycol) 5.0 mg/l (phenol)
Crustacea:	EC ₅₀	48 hours	Daphnia magna (Water flea)	-	-	7.800 mg/l (ethanol) >100 mg/l (ethylene glycol) 3.1 mg/l (phenol)

Trading name:	TB CARBOL FUCHSIN REAGENT				
Product code:	TBC-OT-X**	Date of compilation:	21 Dec 2022	Version:	5

Algae/aquatic plants	IC ₅₀	7 days	green algae	-	-	5.000 mg/l (ethanol) 6.500-13.000 mg/l (ethylene glycol) 61.1 mg/l (phenol)
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	-	-	-
Crustacea:	EC ₅₀	48 hours	No information available	-	-	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	-	-	-
Other organisms	-	-	-	-	-	-

12.2 Persistence and degradability

Abiotic degradation

	Degradation half-lives	Method	Evaluation	Note
Marine water	No information available	No information available	No information available	-
Fresh water	No information available	No information available	No information available	-
Air	No information available	No information available	No information available	-
Soil	No information available	No information available	No information available	-

Biodegradation

% Degradation	Time (days)	Method	Evaluation	Note
94% (ethanol)	No information available	OECD 301E	No information available	readily biodegradable
85% (phenol)	14 days	OECD 301C	No information available	readily biodegradable

12.3 Bioaccumulative potential

Octanol-water partition coefficient (log Kow)

Value	Concentration	pH	°C	Method	Evaluation	Note
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Trading name:	TB CARBOL FUCHSIN REAGENT				
Product code:	TBC-OT-X**	Date of compilation:	21 Dec 2022	Version:	5

-	-	-	-	-	-	bioaccumulation is not expected
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Bioconcentration factor (BCF)						
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Value	Species	Method	Evaluation	Note
No information available	No information available	No information available	No information available	-

Chronic ecotoxicity						
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Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC ₅₀	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea (<i>Daphnia</i>)	EC ₅₀	No information available	No information available	No information available	No information available	-

12.4	Mobility in soil
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	Known or predicted distribution in environmental compartments:
	No information available

	Surface tension:
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Value	°C	Concentration	Method	Note
No information available	No information available	No information available	No information available	-

Adsorption / desorption						
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Transport	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-water	No information available	No information available	No information available	No information available	-
Water-air	No information available	No information available	No information available	No information available	-

Trading name:	TB CARBOL FUCHSIN REAGENT				
Product code:	TBC-OT-X**	Date of compilation:	21 Dec 2022	Version:	5

Soil-air	No information available	No information available	No information available	No information available	-
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12.5 Results of PBT and vPvB assessment

Based on available data, the product does not contain any PBT or vPvB substances.

12.6. Endocrine disrupting properties

Based on available data, does not contain endocrine disruptors.

12.7. Other adverse effects

No further relevant information available.

SECTION 13. Disposal considerations

13.1 Waste treatment methods

13.1.1. Product/Packaging disposal:

Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.

13.1.2. Waste codes/waste designations according to Law:

15 01 10*: Packaging that contains residual hazardous substances or is contaminated with hazardous substances

13.1.3. Waste treatment – relevant information:

No information available

13.1.4. Sewage disposal – relevant information:

Waste must not be disposed of into the sewage system.

13.1.5. Other disposal recommendations:

Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge.

13.1.6. Relevant Community provisions:

Disposal must be made according to official regulations.

SECTION 14 TRANSPORT INFORMATION

Trading name:	TB CARBOL FUCHSIN REAGENT				
Product code:	TBC-OT-X**	Date of compilation:	21 Dec 2022	Version:	5

Transporting/shipment by road (ADR)	
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (ethanol, phenol)
Transport hazard class(es):	3 (6.1)
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by rail (RID)	
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (ethanol, phenol)
Transport hazard class(es):	3 (6.1)
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Inland waterway transport (ADN)	
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (ethanol, phenol)
Transport hazard class(es):	3 (6.1)
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by sea (IMDG)	
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (ethanol, phenol)
Transport hazard class(es):	3 (6.1)
Packing group:	III
Environmentally hazardous:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-
Transporting/shipment by air (ICAO-TI/IATA-DGR)	
UN number:	1992
UN proper shipping name:	Flammable liquid, toxic, n.o.s. (ethanol, phenol)
Transport hazard class(es):	3 (6.1)
Packing group:	III
Environmentally hazardous:	-

Trading name:	TB CARBOL FUCHSIN REAGENT				
Product code:	TBC-OT-X**	Date of compilation:	21 Dec 2022	Version:	5

Special precautions for user:	-
Further information:	-

SECTION 15. Regulatory information

15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture	
	EU regulations	
	Authorization and/or restrictions of use	
	Authorizations:	-
	Restrictions:	-
	Other EU regulations:	<p>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;</p> <p>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;</p> <p>Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;</p> <p>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
	National legislation:	<p>Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act</p>
15.2	Chemical safety assessment	
	None	

SECTION 16. Other information

16.1	Indication of changes:	-
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Trading name:	TB CARBOL FUCHSIN REAGENT				
Product code:	TBC-OT-X**	Date of compilation:	21 Dec 2022	Version:	5

16.2	Abbreviations and acronyms:	<p>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p> <p>IATA: International Air Transport Association</p> <p>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</p> <p>EINECS: European Inventory of Existing Commercial Chemical Substances</p> <p>CAS: Chemical Abstracts Service (division of the American Chemical Society)</p> <p>DNEL: Derived No-Effect Level (UK REACH)</p> <p>LC50: Lethal concentration, 50 percent</p> <p>LD50: Lethal dose, 50 percent</p> <p>PBT: Persistent, Bioaccumulative and Toxic</p> <p>vPvB: very Persistent and very Bioaccumulative</p>
16.3.	Key literature references and source of data:	-
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)	
	Classification	Classification procedure
	-	-
16.5.	Relevant H statements (number and full text)	
	H225	Highly flammable liquid and vapor.
	H226	Flammable liquid and vapor.
	H301	Toxic if swallowed.
H:	H302	Harmful if swallowed.
	H311	Toxic in contact with skin.
	H314	Causes severe skin burns and eye damage.
	H331	Toxic if inhaled.
	H341	Suspected of causing genetic defects.
	H373	May cause damage to organs through prolonged or repeated exposure.
16.6.	Training advice:	-
16.7.	Further information:	<p>** "X" in the product code marks different volumes (different packagings of the product)</p> <p>We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.</p>

ANNEX: Exposure scenario resulting to chemical safety assessment

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Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	21 Dec 2022	Version:	5


SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1	Product identifier	
	Trading name:	TB DECOLORIZER
	Chemical name:	-
	Catalogue number:	TBD-OT-X**
1.2	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use in TB-Stain Cold and TB-Stain Hot kit.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes.
1.3	Details of the supplier of the safety data sheet	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Telefax.:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2. Hazards identification

2.1	Classification of the substance or mixture	
2.1.1	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statements*:
	Flam. Liq. 2	H225
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see SECTION 16		
2.2	Label elements	
	Product identification:	TB DECOLORIZER
	Identification number:	-
	Authorization number:	-

Trading name:	TB DECOLORIZER			
Product code:	TBD-OT-X**	Revision date:	21 Dec 2022	Version: 5

Hazard pictograms:	
	GHS02
Signal word:	Danger
Hazard statements:	H225 Highly flammable liquid and vapor.
Precautionary statements:	P210 Keep away from heat, hot sparks, open flames and other ignition sources. No smoking. P233 Keep container tightly closed. P280 Wear protective gloves/protective clothing/eye/protection/face protection.
Supplemental hazard information (EU):	-
2.3	Other hazards
	<p>The product has no other known specific hazards for human or environment.</p> <p>Results of PBT and vPvB assessment: Based on available data, the product does not contain any PBT or vPvB substances.</p> <p>Endocrine disrupting property: Based on available data, does not contain endocrine disruptors.</p>

SECTION 3. Composition/information on ingredients

CAS/ EC/ Index number	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
64-17-5/ 200-578-6/ 603-002-00-5	01-2119457610-43- 0147	70 - 90 %	ethanol	Flam. Liq. 2; H225
7647-01-0/ 231-595-7/ 017-002-00-2	-	2 -3 %	hydrochloric acid, 37%	Skin Corr. 1B; H314 STOT SE 3; H335

SECTION 4. First aid measures

4.1	Description of first aid measures	
General notes:	If the suggested first aid measures do not prove sufficient, seek medical attention.	
Following inhalation:	Take the victim into fresh air, loosen his clothes and place him in a comfortable position. If breathing difficulty occurs, administer artificial respiration. In case of complaints call a physician.	

Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	21 Dec 2022	Version:	5

	Following skin contact:	Remove the contaminated clothes. Wash the skin surface under plenty of running water. Seek medical assistance if the symptoms of irritation remain.
	Following eye contact:	In case of contact with eyes flush with water holding eyelids apart and moving the eyeballs (for at least 10 minutes). If the symptoms remain, immediately call in ophthalmologist.
	Following ingestion:	Place the victim in a comfortable position. Rinse the mouth with clean water. If the victim is conscious induce vomiting. Do not give the victim anything orally, and do not induce vomiting if the victim is unconscious or suffers from convulsions.
	Self-protection of the first aider:	-
4.2	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	Inhalation of larger quantities may affect the central nervous system.
	Following skin contact:	Prolonged or repeated dermal contact may cause the defatting and dryness of the skin.
	Following eye contact:	May irritate the eyes.
	Following ingestion:	Ingestion of larger quantities may affect the central nervous system.
4.3	Indication of any immediate medical attention and special treatment needed	
	If larger quantities have entered the body, obtain medical treatment (gastric lavage, activated carbon).	

SECTION 5. Firefighting measures		
5.1	Extinguishing media	
	Suitable extinguishing media:	Extinguishing powder, alcohol-resistant foam, water, carbon-dioxide.
	Unsuitable extinguishing media:	Water with full jet.
5.2	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Highly flammable liquid and vapour. In case of fire, smoke, and other combustion products (carbon monoxide, carbon dioxide) may be formed, the inhalation of such combustion products can have serious adverse effects on health. Vapours may form an explosive mix with air. Vapours may be ignited by open flames, sparks, electrical equipment, or static charge. Vapours may travel to great distances, ignite in contact with ignition sources and flash back to the primer source (container). Vapours of ethyl alcohol mix greatly with air and may form an explosive mixture. Air containing 3.3 – 19 % ethyl alcohol vapours may explode in contact with ignition sources. Diluting the mixture with large amounts of water results in the loss of its flammability (around 10 % concentration of ethyl alcohol).
5.3	Advice for firefighters	
	Wear full protective clothing and self-contained breathing apparatus. Cool the fire affected containers with water spray. Use water spray to dissipate alcohol vapours.	

Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	21 Dec 2022	Version:	5

5.4	Additional information
	-

SECTION 6. Accidental release measures

6.1	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Avoid contact with skin, eyes and clothing and inhaling gases, vapours and aerosols. Ensure adequate ventilation. Vapours may accumulate at floor level in low and confined spaces. Remove all heat, ignition and spark sources, turn off machines. Ignition spark arrestor must not be operated in the danger area. Use spark-proof tools. Be aware of the risk of slipping.	
6.2	Environmental precautions:	
	Dispose of the spillage and the resulting waste according to the applicable environmental regulations. Do not allow the product and the resulting waste to enter sewers/soil/surface or ground water. Notify the respective authorities in accordance with local law in the case of environmental pollution immediately.	
6.3	Methods and material for containment and cleaning up	
6.3.1.	Bundling, covering of drains; capping procedures:	Sand protective barrier or barriers made of similar materials.
6.3.2.	Cleaning up:	Collect the spilled product with inert, non-combustible absorbent (e.g. sand, vermiculite, earth) then place into a suitable, closed, properly labelled chemical waste container for removal/disposal. During the collection, placement, disposal of the waste, wear appropriate individual protective equipment. Flush the remains with plenty of water. The product loses its flammability, if diluted with significant amount of water (approx. 10% solution).
6.3.3.	Other information:	Secure proper ventilation. Do not use incompatible materials (see Section 10).
6.4	Reference to other sections	
	See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.	

SECTION 7. Handling and storage

7.1	Precautions for safe handling
7.1.1.	Protection measures

Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	21 Dec 2022	Version:	5

Measures to prevent fire:	Use in well ventilated storage rooms. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use non-sparkling tools and equipment.
Measures to prevent aerosol and dust generation:	Ensure adequate ventilation.
Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
Other measures:	Protect against electrostatic charges.
7.1.2.	Advice on general occupational hygiene:
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.
7.2	Conditions for safe storage, including any incompatibilities
Technical measures and storage conditions:	Store in a well-ventilated place, protected from sunlight, away from sources of heat and ignition, in its original, unopened and hermetically sealed packaging, away from oxidizing agents, food, feed and articles of consumption.
Packaging materials:	Manufacturer's original packaging.
Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 10).
7.3	Specific end use(s)
Recommendations:	-
Industrial sector specific solutions:	-

SECTION 8. Exposure controls/personal protection

8.1	Control parameters			
Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
Ethanol	64-17-5	1000/-	1900/-	-
Hydrogen chloride	7647-01-0	5/10	8/15	-

Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	21 Dec 2022	Version:	5

Substance name:	-			
EC No:	-	CAS No:	-	

DNEL

Industrial

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	1900 mg/m ³ (ethanol)	-	-	380 mg/m ³ (ethanol)
Dermal	-	-	-	343 mg/kg (ethanol)

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	87 mg/kg bw/day (ethanol)
Inhalation	950 mg/m ³ (ethanol)	-	-	114 mg/m ³ (ethanol)
Dermal	-	-	-	206 mg/kg (ethanol)

PNEC

Environmental protection target	PNEC
Fresh water	0.96 mg/l (ethanol)
Freshwater sediments	3.6 mg/kg (ethanol)
Marine water	0.79 mg/l (ethanol)
Marine sediments	2.9 mg/kg (ethanol)
Food chain	380-720 mg/kg (ethanol)
Microorganisms in sewage treatment	580 mg/l (ethanol)
Soil (agricultural)	0.63 mg/kg (ethanol)
Air	no information available

8.2 Exposure controls

8.2.1. Appropriate engineering controls

Substance/mixture related measures to prevent exposure during identified uses:

In case of a hazardous material with no controlled concentration limit it is the employer's duty to keep concentration levels down to a minimum achievable by existing scientific and technological means, where the hazardous substance poses no harm to workers.

Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	21 Dec 2022	Version:	5

	Structural measures to prevent exposure:	In accordance with Section 7.
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	In pursuance of work is proper foresight needed to avoid spilling onto clothes and floors and to avoid contact with eyes and skin. Use according to general application methods and with adequate ventilation. Use non-sparkling ventilation system. Provide appropriate personal protective equipment, safety shower and eye-wash station.
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Use appropriate, chemical-proof protective glasses/face shield (EN ISO 16321-1:2022, EN 166).
8.2.2.2.	Skin protection	
	Hand protection:	Use appropriate, chemical-resistant protective gloves (EN 374).
	Other skin protection:	Use appropriate protective clothing.
8.2.2.3.	Respiratory protection:	In case of normal usage and ventilation, it is not necessary. If concentration of ethyl alcohol exceeds occupational exposure limits in the air, use a self-contained breathing apparatus. For short contact and if the oxygen content of the air is greater than 18 %, use a protective gas mask with filter A (EN 14837/A1).
8.2.2.4.	Thermal hazards:	No thermal hazards known.
8.2.3.	Environmental exposure controls	
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

	Value	Method
Physical state:	liquid	No information available
Colour:	colourless	No information available

Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	21 Dec 2022	Version:	5

	Odour/odour threshold:	ethanol like/no information available	No information available
	Melting point / freezing point:	No information available	No information available
	Boiling point or initial boiling point and boiling range:	No information available	No information available
	Flammability:	No information available	No information available
	Lower and upper explosion limit:	No information available	No information available
	Flash point:	17 °C	No information available
	Auto-ignition temperature:	No information available	No information available
	Decomposition temperature:	No information available	No information available
	pH:	7.0 – 8.0 (20°C)	No information available
	Kinematic viscosity:	No information available	No information available
	Solubility:	No information available	No information available
	Partition coefficient n-octanol/water (log value):	No information available	No information available
	Vapour pressure:	No information available	No information available
	Density and/or relative density:	No information available	No information available
	Relative vapour density:	No information available	No information available
	Particle characteristics:	No information available	No information available
9.2	Other information		
	-		

SECTION 10. Stability and reactivity

10.1	Reactivity:	See Section 10.5.
10.2	Chemical stability:	Stable within normal temperature and general work conditions.
10.3	Possibility of hazardous reactions:	See Section 10.5.
10.4	Conditions to avoid:	Keep away from heat, sparks, open flames, strong heating and ignition sources. No smoking.
10.5	Incompatible materials:	Strong oxidizing agents (inorganic strong acid, nitric acid, perchlorates, peroxy compounds, perchloric acid, permanganates etc.), alkali metals, alkali earth metals.
10.6	Hazardous decomposition products:	Carbon monoxide and carbon dioxide.

SECTION 11. Toxicological information

11.1	Information on hazard classes as defined in Regulation (EC) No 1272/2008
	Acute toxicity:

Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	21 Dec 2022	Version:	5

Route of exposure:	Method	Species	Dose LD ₅₀ /LC ₅₀ or ATE _{mix}	Exposure time	Results
Oral:	-	rat (ethanol)	LD ₅₀	-	7.060 mg/kg
Dermal:	-	rabbit (ethanol)	LD ₅₀	-	>20.000 mg/l
Inhalation:	-	rat (ethanol)	LC ₅₀	4 h	>8.000 mg/l

Specific target organ toxicity – single exposure (STOT SE):

	Specific effects	Target organ	Note
Oral:	No information available	No information available	-
Dermal:	No information available	No information available	-
Inhalation:	No information available	No information available	-

Aspiration hazard: No information available.

Irritation and corrosion

	Exposure time	Species	Evaluation	Method	Note
Skin corrosion/irritation:	-	-	-	-	-
Serious eye damage/irritation	-	-	-	-	-

Sensitization

Skin sensitization:	No information available.
Respiratory sensitization:	No information available.

Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	Absorption of great quantities may cause dizziness, drunkenness, euphoria, unconsciousness and alcohol poisoning. In case of swallowing great quantities, nausea and vomiting may occur. Repeated or prolonged exposure may lead to liver cirrhosis.
Dermal exposure:	After prolonged or repeated exposure symptoms may include: defatting, dryness and cracking of skin.
Inhalation exposure:	Inhalation of great quantities may cause dizziness, euphoria and mild irritation of the mucous membranes.
Eye exposure:	May cause irritation and redness.

Repeated dose toxicity (subacute, subchronic, chronic)

Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	21 Dec 2022	Version:	5

	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-

Specific target organ toxicity – repeated exposure (STOT RE):

	Specific effects	Target organ	Note
Subacute oral	No information available	No information available	-
Subacute dermal	No information available	No information available	-
Subacute inhalation	No information available	No information available	-
Subchronic oral	No information available	No information available	-
Subchronic dermal	No information available	No information available	-
Subchronic inhalation	No information available	No information available	-
Chronic oral	No information available	No information available	-
Chronic dermal	No information available	No information available	-

Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	21 Dec 2022	Version:	5

Chronic inhalation	No information available	No information available	-
CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)			
Carcinogenicity:	Based on available data, the classification criteria are not met.		
Mutagenicity <i>in vitro</i> :	Based on available data, the classification criteria are not met.		
Genotoxicity:	Based on available data, the classification criteria are not met.		
Mutagenicity <i>in vivo</i> :	Based on available data, the classification criteria are not met.		
Germ cell mutagenicity:	Based on available data, the classification criteria are not met.		
Reproductive toxicity:	Based on available data, the classification criteria are not met.		
Summary of evaluation of the CMR properties:		Based on available data, the classification criteria are not met.	
11.2	Information on other hazards:		
11.2.1.	Endocrine disrupting properties:		
	Based on available data, does not contain endocrine disruptors.		
11.2.2.	Other information:		
	-		

SECTION 12. Ecological information						
12.1 Toxicity						
Acute (short-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	golden orf	No information available	8.140 mg/l /48 h (ethanol)	-
Crustacea:	EC ₅₀	48 hours	daphnia magna	No information available	7.800 mg/l (ethanol)	-
Algae/aquatic plants	IC ₅₀	4 days	algae	No information available	5.000 mg/l / 7d (ethanol)	-
Other organisms	-	-	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note

Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	21 Dec 2022	Version:	5

Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-
Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

12.2	Persistence and degradability
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	Abiotic degradation
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	Degradation half-lives	Method	Evaluation	Note
Marine water	No information available	No information available	No information available	-
Fresh water	No information available	No information available	No information available	-
Air	No information available	No information available	No information available	-
Soil	No information available	No information available	No information available	-

	Biodegradation
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% Degradation	Time (days)	Method	Evaluation	Note
No information available	No information available	No information available	No information available	No information available

12.3	Bioaccumulative potential
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	Octanol-water partition coefficient (log K _{ow})
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Value	Concentration	pH	°C	Method	Evaluation	Note
Log Pow: ~ 0.32	-	-	-	-	-	The product does not bioaccumulate

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Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	21 Dec 2022	Version:	5

Bioconcentration factor (BCF)				
Value	Species	Method	Evaluation	Note
BCF: 0.66	No information available	No information available	No information available	-

Chronic ecotoxicity						
Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC ₅₀	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea (<i>Daphnia</i>)	EC ₅₀	No information available	No information available	No information available	No information available	-

12.4 Mobility in soil

Known or predicted distribution in environmental compartments:						
No information available						
Surface tension:						
Value	°C	Concentration	Method	Note		
No information available	No information available	No information available	No information available	-		

Adsorption / desorption					
Transport	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-water	No information available	No information available	No information available	No information available	-
Water-air	No information available	No information available	No information available	No information available	-
Soil-air	No information available	No information available	No information available	No information available	-

Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	21 Dec 2022	Version:	5

12.5	Results of PBT and vPvB assessment
	Based on available data, the product does not contain any PBT or vPvB substances.

12.6.	Endocrine disrupting properties
	Based on available data, does not contain endocrine disruptors.

12.7.	Other adverse effects
	Do not let the product or its residues reach sewer system, waterways and soil.

SECTION 13. Disposal considerations

13.1	Waste treatment methods
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13.1.1.	Product/Packaging disposal:
	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.

13.1.2.	Waste codes/waste designations according to Law:
	Packaging that contains residual hazardous substances or is contaminated with hazardous substances

13.1.3.	Waste treatment – relevant information:
	No information available

13.1.4.	Sewage disposal – relevant information:
	Waste must not be disposed of into the sewage system.

13.1.5.	Other disposal recommendations:
	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Unused product residues may be burnt.

13.1.6.	Relevant Community provisions:
	Disposal must be made according to official regulations.

SECTION 14 TRANSPORT INFORMATION

	Transporting/shipment by road (ADR)
UN number:	1170
UN proper shipping name:	Ethanol solution

Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	21 Dec 2022	Version:	5

Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-

Transporting/shipment by rail (RID)

UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-

Inland waterway transport (ADN)

UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-

Transporting/shipment by sea (IMDG)

UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:	-

Transporting/shipment by air (ICAO-TI/IATA-DGR)

UN number:	1170
UN proper shipping name:	Ethanol solution
Transport hazard class(es):	3
Packing group:	II
Environmentally hazardous:	-
Special precautions for user:	-

Further information:	-
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Trading name:	TB DECOLORIZER				
Product code:	TBD-OT-X**	Revision date:	21 Dec 2022	Version:	5

SECTION 15. Regulatory information

15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture	
	EU regulations	
	Authorization and/or restrictions of use	
	Authorizations:	-
	Restrictions:	-
	Other EU regulations:	<p>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;</p> <p>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;</p> <p>Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;</p> <p>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;</p> <p>COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
	Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
	National legislation:	<p>Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act</p>
15.2	Chemical safety assessment	
	None	

SECTION 16. Other information

16.1	Indication of changes:	-
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Trading name:	TB DECOLORIZER			
Product code:	TBD-OT-X**	Revision date:	21 Dec 2022	Version: 5

16.2	Abbreviations and acronyms:	<p>ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p> <p>IATA: International Air Transport Association</p> <p>GHS: Globally Harmonised System of Classification and Labelling of Chemicals</p> <p>EINECS: European Inventory of Existing Commercial Chemical Substances</p> <p>CAS: Chemical Abstracts Service (division of the American Chemical Society)</p> <p>DNEL: Derived No-Effect Level (UK REACH)</p> <p>LC50: Lethal concentration, 50 percent</p> <p>LD50: Lethal dose, 50 percent</p> <p>PBT: Persistent, Bioaccumulative and Toxic</p> <p>vPvB: very Persistent and very Bioaccumulative</p>
16.3.	Key literature references and source of data:	-
16.4.	Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)	
	Classification	Classification procedure
	-	-
16.5.	Relevant H statements (number and full text)	
	H:	<p>225 Highly flammable liquid and vapour.</p> <p>314 Causes severe skin burns and eye damage.</p> <p>335 May cause respiratory irritation.</p>
16.6.	Training advice:	-
16.7.	Further information:	<p>** "X" in the product code marks different volumes (different packagings of the product)</p> <p>We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.</p>

ANNEX: Exposure scenario resulting to chemical safety assessment

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Trading name:	TB MALACHITE GREEN REAGENT		
Product code:	TBM-OT-X**	Date of compilation:	14 November 2022
		Version:	4

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1.	Product identifier	
	Trading name:	TB MALACHITE GREEN REAGENT
	Chemical name:	-
	Catalogue number:	TBM-OT-X**
1.2.	Relevant identified uses of the substance or mixture and uses advised against	
	Uses:	For use in TB-Stain Cold kit.
	Uses advised against:	Only the identified uses are advised.
	Reason why uses advised against:	The product is intended for use only as an <i>in vitro</i> diagnostic medical device, registered at the Agency for Medicinal Products and Medical Devices and there is no reason to use it for other purposes
1.3.	Details of the supplier of the safety data sheet	
	Supplier:	BioGnost Ltd.
	Address:	Medjugorska 59, Zagreb
	Telephone number:	+385 1 2409997
	Fax no.:	+385 1 2404039
	e-mail of competent person:	msds@biognost.hr
	National contact:	-
1.4.	Emergency telephone number	
	National Protection and Rescue Directorate:	112
	Medical information:	+385 1 2348 342
	Other information:	-

SECTION 2. Hazards identification

2.1.	Classification of the substance or mixture	
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)	
	Hazard class and category code:	Hazard statements*:
	Not identified as hazardous substance.	-
2.1.2.	Additional information	
	-	
*For full text of Hazard- and EU Hazard-statements: see Section 16		
2.2.	Label elements	
	Product identification:	TB MALACHITE GREEN REAGENT
	Identification number:	-
	Authorization no.:	-
	Hazard pictograms:	-

Trading name:	TB MALACHITE GREEN REAGENT			
Product code:	TBM-OT-X**	Date of compilation:	14 November 2022	Version: 4

Signal word:	-
Hazard statements:	-
Precautionary statements:	-
Supplemental hazard information (EU):	-

2.3.	Other hazards
Endocrine Disrupting Properties:	
No known endocrine disrupting properties.	

SECTION 3. Composition/information on ingredients				
CAS/ EC/ Index no.	REACH Registration No	Weight % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
2437-29-8/ 219-441-7/ 602-096-00-5	-	< 0.25%	bis[[4-[4-(dimethylamino)benzhydrylide ne] cyclohexa-2,5-dien-1- ylidene]dimethylammonium] oxalate, dioxalate	Acute Tox. 4; H302 Eye Dam. 1; H318 Repr. 2; H361d Aquatic Acute 1; H400 Aquatic Chronic 1; H410

SECTION 4. First aid measures	
4.1.	Description of first aid measures
General notes:	-
Following inhalation:	Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. If breathing becomes erratic or it stops, immediately apply artificial respiration (other than mouth-to-mouth) and contact a physician.
Following skin contact:	Remove contaminated clothing. Immediately wash with plenty of water and soap. Seek medical assistance if the symptoms of irritation remain.
Following eye contact:	Rinse out with plenty of water with the eyelid held wide open using clean fingers. If the symptoms remain, immediately call a physician.
Following ingestion:	Do not induce vomiting. Make the afflicted person drink a glass of water. If spontaneous vomiting occurs, wash the mouth with water, then make the person drink 100-200 ml of water and seek medical attention.
Self-protection of the first aider:	Treat symptomatically.
4.2.	Most important symptoms and effects, both acute and delayed
Following inhalation:	Allergic persons may display irritation after prolonged or repeated exposure.

Trading name:	TB MALACHITE GREEN REAGENT		
Product code:	TBM-OT-X**	Date of compilation:	14 November 2022
		Version:	4

	Following skin contact:	Allergic persons may display irritation.
	Following eye contact:	May cause irritation.
	Following ingestion:	Swallowing may cause discomfort in abdomen and abdominal pains.
4.3.	Indication of any immediate medical attention and special treatment needed	
	-	

SECTION 5. Firefighting measures		
5.1.	Extinguishing media	
	Suitable extinguishing media:	Small fire - water spray, dry powder, CO ₂ Large fire - water spray or alcohol-resistant foam
	Unsuitable extinguishing media:	water jet
5.2.	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	No information available
5.3.	Advice for firefighters	
	Use a self-contained open-circuit compressed air breathing apparatus and fireproof clothing. Cool closed containers exposed to fire with water spray or vapor.	
5.4.	Additional information	
	Remove sources of heat and ignition. Do not contaminate the environment with extinguishing media.	

SECTION 6. Accidental release measures		
6.1.	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	Use personal protective equipment (see Section 8).
	Accident prevention methods:	Evacuate members of all non-essential personnel and those members without protective equipment. Remove all sources of sparks and ignition. Do not smoke.
	Emergency procedures:	Mark the area using proper signs.
6.1.2.	For emergency responders:	
	Wear protective equipment (see Section 8).	
6.2.	Environmental precautions:	
	Do not dispose of in sewage, drainage system and waterways. In case of large spillage contact National Protection and Rescue Directorate (NPRD) on 112.	
6.3.	Methods and material for containment and cleaning up	
6.3.1.	Bundling, covering of drains; capping procedures:	Sand or clay barriers.

Trading name:	TB MALACHITE GREEN REAGENT			
Product code:	TBM-OT-X**	Date of compilation:	14 November 2022	Version: 4

6.3.2.	Cleaning up:	Where possible, the substance can be absorbed by using inflammable material (sand, diatomaceous earth, vermiculite). Place the waste material in tightly closed impermeable containers. Store the substance in well ventilated storage rooms until disposal. Submit for disposal to the legal persons authorized by the Ministry of Environmental and Nature Protection. After disposal of the products, wash the area and involved materials with water.
6.3.3.	Other information:	-
6.4.	Reference to other sections	
	See Section 7 for information about secure handling. See Section 8 for information about personal protective equipment. See Section 13 for information about containment.	

SECTION 7. Handling and storage		
7.1.	Precautions for safe handling	
7.1.1.	Protection measures	
	Measures to prevent fire:	Keep away from sources of heat and ignition. Do not smoke.
	Measures to prevent aerosol and dust generation:	Secure proper ventilation.
	Measures to protect the environment:	Prevent spilling into the sewage system and waterways.
	Other measures:	-
7.1.2.	Advice on general occupational hygiene:	
	Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating.	
7.2.	Conditions for safe storage, including any incompatibilities	
	Technical measures and storage conditions:	Keep in tightly closed and upright set containers in a well ventilated storage rooms, and away from sources of heat, sunlight, and other incompatible substances.
	Packaging materials:	Manufacturer's original packaging.
	Requirements for storage rooms and vessels:	Keep away from food and drink. Keep the containers tightly closed.
	Advices for storage equipment:	The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation.
	Further information on storage conditions:	Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 9).
7.3.	Specific end use(s)	
	Recommendations:	-

Trading name:	TB MALACHITE GREEN REAGENT				
Product code:	TBM-OT-X**	Date of compilation:	14 November 2022	Version:	4

Industrial sector specific solutions:	-
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SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Substance	CAS No	Occupational exposure limit values/short term values		Biological limit values
		ppm	mg/m ³	
-	-	-	-	No information available

Substance name:	-
EC No:	-
CAS No:	-

DNEL

Industrial

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

Critical physical parameters: solubility, flammability, corrosivity:	-
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Consumer

Route of exposure:	Acute effect local	Acute effect systemic	Chronic effect local	Chronic effect systemic
Oral	-	-	-	-
Inhalation	-	-	-	-
Dermal	-	-	-	-

PNEC

Environmental protection target	PNEC
Fresh water	No information available
Freshwater sediments	No information available
Marine water	No information available
Marine sediments	No information available
Food chain	No information available
Microorganisms in sewage treatment	No information available
Soil (agricultural)	No information available
Air	No information available

Trading name:	TB MALACHITE GREEN REAGENT				
Product code:	TBM-OT-X**	Date of compilation:	14 November 2022	Version:	4

8.2.		Exposure controls
8.2.1.		Appropriate engineering controls
	Substance/mixture related measures to prevent exposure during identified uses:	Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace.
	Structural measures to prevent exposure:	No information available
	Organisational measures to prevent exposure:	Organization of work in order to reduce other worker's influence during work process.
	Technical measures to prevent exposure:	Secure proper workspace ventilation in order to keep concentration levels in air below permitted levels.
8.2.2.		Personal protection equipment
8.2.2.1.	Eye and face protection:	Safety glasses that stick to face (preventing splashing) (EN 166) or visor.
8.2.2.2.	Skin protection	
	Hand protection:	Protective gloves must be according to the EU Directive 2016/425/EEC and standard EN 374. Glove material: nitrile rubber Glove thickness: ≥0.50 mm Break through time: >480 min
	Other skin protection:	Wear antistatic clothing made of natural fibers (such as cotton) with long sleeves (EN 13034), and shoes that cover the entire foot (EN 10335).
8.2.2.3.	Respiratory protection:	Protective full face mask (EN 136) or half mask (EN 140) equipped with a filter for organic vapors, type "A" (boiling point >65°C) according to EN 14387) used when concentration levels exceed GVI.
8.2.2.4.	Thermal hazards:	No information available
8.2.3.		Environmental exposure controls
	Substance/mixture related measures to prevent exposure:	See Section 6
	Structural measures to prevent exposure:	Use modern equipment.
	Organisational measures to prevent exposure:	Adapt the work process to the required working conditions of the workplace.
	Technical measures to prevent exposure:	See Section 6

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Trading name:	TB MALACHITE GREEN REAGENT		
Product code:	TBM-OT-X**	Date of compilation:	14 November 2022
		Version:	4

	Value	Method
Physical state:	liquid	No information available
Color:	blue-green	No information available
Odour/odour threshold:	no odor/no information available	No information available
Melting point / freezing point:	No information available	No information available
Boiling point or initial boiling point and boiling range:	No information available	No information available
Flammability:	No information available	No information available
Lower and upper explosion limit:	No information available	No information available
Flash point:	No information available	No information available
Auto-ignition temperature:	No information available	No information available
Decomposition temperature:	No information available	No information available
pH:	No information available	No information available
Kinematic viscosity:	No information available	No information available
Solubility:	No information available	No information available
Partition coefficient n-octanol/water (log value):	No information available	No information available
Vapour pressure:	No information available	No information available
Density and/or relative density	No information available	No information available
Relative vapour density:	No information available	No information available
Particle characteristics:	No information available	No information available
9.2. Other information		
-		

SECTION 10.: Stability and reactivity

10.1.	Reactivity:	See subsections 10.3 through 10.5.
10.2.	Chemical stability:	The product is chemically stable under standard ambient conditions of storing and using.
10.3.	Possibility of hazardous reactions:	No information available.
10.4.	Conditions to avoid:	No information available.
10.5.	Incompatible materials:	No information available.
10.6.	Hazardous decomposition products:	No information available.

SECTION 11. Toxicological information

11.1.	Information on hazard classes as defined in Regulation (EC) No 1272/2008
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Trading name:	TB MALACHITE GREEN REAGENT				
Product code:	TBM-OT-X**	Date of compilation:	14 November 2022	Version:	4

Acute toxicity:

Route of exposure:	Method	Species	Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture}	Exposure time	Results
Oral exposure:	No information available	-	LD ₅₀	-	-
Dermal exposure:	No information available	-	LD ₅₀	-	-
Inhalation exposure:	No information available	-	LC ₅₀	-	-

Specific target organ toxicity – single exposure (STOT SE):

	Specific effects	Target organ	Note
Oral exposure:	No information available	No information available	-
Dermal exposure:	No information available	No information available	-
Inhalation exposure:	No information available	No information available	-

Aspiration hazard: No information available

Irritation and corrosion:

	Exposure time	Species	Evaluation	Method	Note
Skin irritation:	-	rabbit	-	-	-
Eye irritation:	-	rabbit	-	-	-

Sensitization

Dermal exposure:	No information available
Inhalation exposure:	No information available

Symptoms related to the physical, chemical and toxicological characteristics

Oral exposure:	Swallowing may cause discomfort in abdomen and abdominal pains.
Dermal exposure:	Allergic persons may display irritation.
Inhalation exposure:	Allergic persons may display irritation after prolonged or repeated exposure.
Eye exposure:	May cause irritation.

Repeated dose toxicity (subacute, subchronic, chronic)

Trading name:	TB MALACHITE GREEN REAGENT			
Product code:	TBM-OT-X**	Date of compilation:	14 November 2022	Version: 4

	Dose	Exposure time	Species	Method	Evaluation	Note
Subacute oral	No information available	No information available	No information available	No information available	No information available	-
Subacute dermal	No information available	No information available	No information available	No information available	No information available	-
Subacute inhalation	No information available	No information available	No information available	No information available	No information available	-
Subchronic oral	No information available	No information available	No information available	No information available	No information available	-
Subchronic dermal	No information available	No information available	No information available	No information available	No information available	-
Subchronic inhalation	No information available	No information available	No information available	No information available	No information available	-
Chronic oral	No information available	No information available	No information available	No information available	No information available	-
Chronic dermal	No information available	No information available	No information available	No information available	No information available	-
Chronic inhalation	No information available	No information available	No information available	No information available	No information available	-

Specific target organ toxicity – repeated exposure (STOT RE):

	Specific effects	Target organ	Note
Subacute oral	No information available	No information available	-
Subacute dermal	No information available	No information available	-
Subacute inhalation	No information available	No information available	-
Subchronic oral	No information available	No information available	-
Subchronic dermal	No information available	No information available	-
Subchronic inhalation	No information available	No information available	-
Chronic oral	No information available	No information available	-
Chronic dermal	No information available	No information available	-

Trading name:	TB MALACHITE GREEN REAGENT			
Product code:	TBM-OT-X**	Date of compilation:	14 November 2022	Version: 4

Chronic inhalation	No information available	No information available	-
CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)			
Carcinogenicity:	Current studies on test animals did not indicate carcinogenic effects.		
Mutagenicity <i>in-vitro</i> :	Current <i>in vitro</i> tests did not indicate mutagenic effects.		
Genotoxicity:	No information available		
Mutagenicity <i>in-vivo</i> :	Current <i>in vivo</i> tests did not indicate mutagenic effects.		
Germ cell mutagenicity:	No information available		
Reproductive toxicity:	No toxicity on reproductive organs was determined in reproductive organs.		
Summary of evaluation of the CMR properties: -			
11.2. Information on other hazards:			
11.2.1. Endocrine disrupting properties:			
No known endocrine disrupting properties that affect human health.			
11.2.2. Other information:			
-			

SECTION 12. Ecological information						
12.1. Toxicity						
Acute toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	-	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	-	-
Algae/aquatic plants	IC ₅₀	8 days	No information available	No information available	-	-
Microorganisms	LC ₅₀	72 hours	-	-	-	-
Chronic (long-term) toxicity	Dose	Exposure time	Species	Method	Evaluation	Note
Fish	LC ₅₀	96 hours	No information available	No information available	No information available	-
Crustacea:	EC ₅₀	48 hours	No information available	No information available	No information available	-

Trading name:	TB MALACHITE GREEN REAGENT				
Product code:	TBM-OT-X**	Date of compilation:	14 November 2022	Version:	4

Algae/aquatic plants	IC ₅₀	72 hours	No information available	No information available	No information available	-
Other organisms	-	-	-	-	-	-

12.2. Persistence and degradability

Abiotic degradation				
	Degradation half-lives	Method	Evaluation	Note
Marine water	No information available	No information available	No information available	-
Fresh water	No information available	No information available	No information available	-
Air	No information available	No information available	No information available	-
Soil	No information available	No information available	No information available	-

Biodegradation				
% Degradation	Time (days)	Method	Evaluation	Note
No information available	No information available	No information available	No information available	No information available

12.3. Bioaccumulative potential

Octanol-water partition coefficient (log K _{ow})						
Value	Concentration	pH	°C	Method	Evaluation	Note
-	No information available	-	-	No information available	No information available	-

Bioconcentration factor (BCF)				
Value	Species	Method	Evaluation	Note
No information available	No information available	No information available	No information available	No information available

Chronic ecotoxicity

Trading name:	TB MALACHITE GREEN REAGENT				
Product code:	TBM-OT-X**	Date of compilation:	14 November 2022	Version:	4

Value	Dose	Exposure time	Species	Method	Evaluation	Note
Chronic toxicity on fish	LC ₅₀	No information available	No information available	No information available	No information available	-
Chronic toxicity on crustacea (<i>Daphnia</i>)	EC ₅₀	No information available	No information available	No information available	No information available	-

12.4. Mobility in soil

Known or predicted distribution in environmental compartments:

No information available

Surface tension:

Value	°C	Concentration	Method	Note
No information available	No information available	No information available	No information available	-

Adsorption / desorption

Transport	A/D coefficient Henry's constant	log Kow	Evaporation rate	Method	Note
Soil-water	No information available	No information available	No information available	No information available	-
Water-air	No information available	No information available	No information available	No information available	-
Soil-air	No information available	No information available	No information available	No information available	-

12.5. Results of PBT and vPvB assessment

No information available

12.6. Endocrine disrupting properties

No known endocrine disrupting properties that affect the environment.

Trading name:	TB MALACHITE GREEN REAGENT			
Product code:	TBM-OT-X**	Date of compilation:	14 November 2022	Version: 4

12.7.	Other adverse effects	No adverse effects are expected.
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SECTION 13. Disposal considerations

13.1.	Waste treatment methods	
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13.1.1.	Product/Packaging disposal:	Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.
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13.1.2.	Waste codes/waste designations according to Law:	No information available
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13.1.3.	Waste treatment – relevant information:	No information available
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13.1.4.	Sewage disposal – relevant information:	Waste must not be disposed of into the sewage system.
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13.1.5.	Other disposal recommendations:	Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge. Do not dispose of in places where ignition may occur.
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13.1.6.	Relevant Community provisions:	-
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SECTION 14. Transport information

Transporting/shipment by road (ADR)	
UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-
Transporting/shipment by rail (RID)	

Trading name:	TB MALACHITE GREEN REAGENT				
Product code:	TBM-OT-X**	Date of compilation:	14 November 2022	Version:	4

UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-

Inland waterway transport (ADN)

UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-

Transporting/shipment by sea (IMDG)

UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-

Transporting/shipment by air (ICAO-TI/IATA-DGR)

UN number:	Not subject to transport regulations.
UN proper shipping name:	-
Transport hazard class(es):	-
Packing group:	-
Environmentally hazardous:	-
Special precautions for user:	-

Further information:	The product is not subject to classification.
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SECTION 15. Regulatory information

15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture	
	EU regulations	
	Authorization and/or restrictions of use	
	Authorizations:	-

Trading name:	TB MALACHITE GREEN REAGENT				
Product code:	TBM-OT-X**	Date of compilation:	14 November 2022	Version:	4

Restrictions:	-
Other EU regulations:	<p>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;</p> <p>Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC;</p> <p>Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work;</p> <p>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;</p> <p>REACH Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII);</p>
Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline)	
National legislation:	<p>Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act</p>
15.2. Chemical safety assessment	
	None

SECTION 16. Other information											
16.1. Indication of changes:	-										
16.2. Abbreviations and acronyms:	<table> <tr> <td>PBT</td> <td>Stable, bioaccumulative and toxic</td> </tr> <tr> <td>vPvB</td> <td>Strongly stable and strongly bioaccumulative.</td> </tr> <tr> <td>LD₅₀</td> <td>Lethal dose, 50%</td> </tr> <tr> <td>LC₅₀</td> <td>Lethal concentration, 50%</td> </tr> <tr> <td>STOT-SE</td> <td>Specific target organ toxicity - single exposure</td> </tr> </table>	PBT	Stable, bioaccumulative and toxic	vPvB	Strongly stable and strongly bioaccumulative.	LD ₅₀	Lethal dose, 50%	LC ₅₀	Lethal concentration, 50%	STOT-SE	Specific target organ toxicity - single exposure
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STOT-SE	Specific target organ toxicity - single exposure										
16.3. Key literature references and source of data:	-										
16.4. Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP)											
Classification	Classification procedure										
-	-										
16.5. Relevant H statements (number and full text)											

Trading name:	TB MALACHITE GREEN REAGENT				
Product code:	TBM-OT-X**	Date of compilation:	14 November 2022	Version:	4

H:	-	-
16.6.	Training advice:	-
16.7.	Further information:	<p>** "X" in the product code marks different volumes (different packagings of the product)</p> <p>We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet.</p>

ANNEX: Exposure scenario resulting to Chemical safety assessment	
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